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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte CHARLES JOEL ARNTZEN and DOMINIC MAN-KIT LAM

Appeal 2010-000526
Application 10/733,135
Technology Center 1600

Before DONALD E. ADAMS, DEMETRA J. MILLS, and
MELANIE L. McCOLLUM, *Administrative Patent Judges*.

MILLS, *Administrative Patent Judge*.

DECISION ON APPEAL[1]

This is an appeal under 35 U.S.C. § 134. The Examiner has rejected the claims for obviousness. We have jurisdiction under 35 U.S.C. § 6(b).

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[1] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the "MAIL DATE" (paper delivery mode) or the "NOTIFICATION DATE" (electronic delivery mode) shown on the PTOL-90A cover letter attached to this decision.

STATEMENT OF THE CASE

The following claim is representative and reads as follows:

1. A method of producing an immunogenic composition comprising transforming a plant with a nucleic acid construct that expresses a recombinant mammalian viral immunogen in a plant,
selecting those plants expressing said recombinant viral immunogen at a level such that upon oral administration of a composition comprising a plant-expressed recombinant viral immunogen to an animal, an immunogenic response to said viral immunogen is elicited so that the animal is protected against viral challenge, and
producing from said plants said immunogenic composition.

Cited References

The Examiner relies on the following prior art references to show unpatentability:

Goodman et al. U.S. 4,956,282 Sep. 11, 1990

Kapikian et al., *Prospects for Development of a Rotavirus Vaccine Against Rotavirus Diarrhea in Infants and Young Children*, Reviews of Infectious Diseases, Vol 11, Supp. 3, pp. S539-S546 (1989).

Kay et al., *Duplication of CaMV 35S Promoter Sequences Creates a Strong Enhancer for Plant Genes*, 236 Science, pp.1299-1302 (1987).

Gallie et al., *Post-transcriptional regulation in higher eukaryotes: The role of the reporter gene in controlling expression*, Mol Gen Genet 228: 258-264 (1991).

Grounds of Rejection

1. Claims 1-5, 7, 8, and 10 are rejected under 35 U.S.C. §103(a) for obviousness over Goodman in view of Kapikian.
2. Claims 6 and 9 are rejected under 35 U.S.C. §103(a) for obviousness over Goodman in view of Kapikian, Kay and Gallie.

Discussion

1. Claims 1-5, 7, 8, and 10 are rejected under 35 U.S.C. §103(a) for obviousness over Goodman in view of Kapikian.

ISSUE

The Examiner concludes that:

> [g]iven the recognition of those of ordinary skill in the art of the value of expressing an immunogenic protein in a plant as taught by Goodman et al (see column 3, lines 31-42), it would have been obvious to one of ordinary skill in the art to use the method of Goodman et al and to modify said method using the sequences encoding immunogens from the rotovirus taught by Kapikian et al. One would have been motivated to express immunogens from the rotovirus taught by Kapikian et al because they teach that it is important to find a safe, inexpensive, and effective rotavirus vaccine (see page S539, left column, first paragraph) because such a vaccine can prevent diarrheal diseases that cause about 12,600 deaths per day (see page, 3539, paragraph bridging left and right columns).

(Ans. 7.)

Appellants argue "Goodman et al. do not teach expressing an immunogen, much less expressing an immunogen in a plant at such a level that when a composition comprising the immunogen is consumed by an animal the composition elicits an immune response in the animal. Kapikian et al. fail to supply the teachings that are lacking in Goodman et al." (App. Br. 5).

The issue is: Does the cited prior art teach expressing an immunogen, in a plant at such a level that when a composition comprising the immunogen is consumed by an animal the composition elicits an immune response in the animal?

FINDINGS OF FACT

1. "Goodman et al teach the production of recombinant proteins in plants, including proteins encoded by mammalian viral pathogen genes (see column 3, lines 11-13). They suggest that antigens associated with viral pathogens could be expressed (see column 3, lines 31-32). Antigens are also referred to in the art as immunogens (see page 9 of the instant specification, line 2)." (Ans. 6.)

2. Goodman et al. "teach that in some instances the recombinant protein can have a physiological effect on ingestion, and it will be sufficient for the product to be retained in an edible plant part (see column 5, lines 51-56)." (*Id.*)

3. Goodman et al. "teach that plants that can be employed for the production of recombinant proteins may be either monocots or dicots (see column 4, lines 55-56), that the DNA construct can be transferred into the plant cell by *A. tumefaciens*, or *A. rhizogenes*, microinjection, liposome fusion, or viral infection (see column 4, lines 43-45) which are all means of transforming a plant with a construct." (*Id.*)

4. "Goodman et al teach transcriptional initiation regions (also referred to as promoters), including the napin promoter for expression in seeds (which is an edible tissue of a plant) (see column 2, lines 43-58). They suggest the use of several different species of plants that are edible by an animal, including sunflower, corn, sugar cane, soybean, tomato, alfalfa, mustard, and sugar beet (see column 4, lines 59-60)." (*Id.*)

5. Goodman et al. "teach detection of the recombinant protein produced and measurement of the activity of the recombinant protein (see columns 9 and 10)." (*Id.*)

6. "Goodman et al do not teach an immunogen from a transmissible gastroenteritis virus, nor do they teach an immunogen that is capable of generating an immunogenic response when it interacts with a mucosal membrane." (*Id.* at 7.)

7. "Kapikian et al teach an immunogen from a transmissible gastroenteritis virus that is capable of generating an immunogenic response when it interacts with a mucosal membrane, (see pages S542-S543 for a discussion of candidate vaccines, and see page S542, right column, last paragraph, where i[t] states that the vaccine was shown to be safe and antigenic after oral administration which shows that i[t] generates an immunogenic response when it interacts with a mucosal membrane). This demonstrates that it has a physiological effect on ingestion." (*Id.*)

8. The Examiner concludes that "[g]iven the recognition of those of ordinary skill in the art of the value of expressing an immunogenic protein in a plant as taught by Goodman et al (see column 3, lines 31-42), it would have been obvious to one of ordinary skill in the art to use the method of Goodman et al and to modify said method using the sequences encoding immunogens from the rotovirus taught by Kapikian et al." (*Id.*)

9. The Examiner concludes that "[o]ne would have been motivated to express immunogens from the rotovirus taught by Kapikian et al because they teach that it is important to find a safe, inexpensive, and effective rotavirus vaccine (see page S539, left column, first paragraph) because such

a vaccine can prevent diarrheal diseases that cause about 12,600 deaths per day (see page, S539, paragraph bridging left and right columns)." (*Id.*)

10. "Kipikian et al specifically state that an orally administered vaccine would be the most effective (see page S541, left column, first paragraph) and Goodman et al specifically suggest that their method can be utilized to grow recombinant viral antigens (see column 3, lines 31-35) and they teach that it could be used for expression in an edible plant part for proteins that can have a physiological effect on ingestion (see column 5, lines 51-56)." (*Id.* at 7-8.)

11. The Examiner concludes that "it would have been obvious to select the plants with the highest expression levels because common sense dictates that having a higher expression level would be desirable; and the highest producers would have the ability to generate an immunogenic response sufficient to protect against a viral challenge after oral administration of the plant or plant parts." (*Id.* at 8.)

12. "Given the success of producing recombinant therapeutic proteins in plants taught by Goodman et al and the success of utilizing recombinant proteins for vaccines as taught by Kapikian et al, one would expect success in combining the teachings." (*Id.*)

PRINCIPLES OF LAW

The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) secondary considerations of nonobviousness, if any. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). The Supreme Court has emphasized that "the [obviousness] analysis need

not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR Int'l v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007).

ANALYSIS

We essentially agree with the Examiner's fact finding, statement of the rejection and responses to Appellants' arguments as set forth in the Answer. We provide the following comments for emphasis.

The Examiner concludes that "[g]iven the recognition of those of ordinary skill in the art of the value of expressing an immunogenic protein in a plant as taught by Goodman et al (see column 3, lines 31-42), it would have been obvious to one of ordinary skill in the art to use the method of Goodman et al and to modify said method using the sequences encoding immunogens from the rotovirus taught by Kapikian et al." (Ans. 7.)

The Examiner concludes that "[c]laim 1 includes 'selecting those plants expressing said recombinant viral immunogen at a level such that upon oral administration of a composition comprising a plant-expressed recombinant viral immunogen to an animal, an immunogenic response to said viral immunogen is elicited'. The office interprets this recitation to be inclusive of selecting plants with any expression level of a viral immunogen because the composition can comprise recombinant viral immunogen that has been purified and/or concentrated; therefore the amount of immunogen in the composition is not related to the level of expression in the plant." (*Id.* at 5.)

Appellants argue "Goodman et al. do not teach expressing an immunogen, much less expressing an immunogen in a plant at such a level that when a composition comprising the immunogen is consumed by an animal the composition elicits an immune response in the animal. Kapikian et al. fail to supply the teachings that are lacking in Goodman et al." (App. Br. 7.)

We are not persuaded by Appellants' argument. We agree with the Examiner's interpretation of the claim 1 language, "selecting those plants expressing said recombinant viral immunogen at a level such that upon oral administration of a composition comprising a plant-expressed recombinant viral immunogen to an animal, an immunogenic response to said viral immunogen is elicited so that the animal is protected against viral challenge."

According to the Examiner, claim 1

> does not specify the quantity of immunogen to be administered (10 micrograms, 10 milligrams, 10 grams, a kilogram), it does not specify the quantity of plant material from which the immunogen will be taken (grams or tons) or the quantity of plant material which will be administered for claims 8 and 9, it does not specify the amount of protection against viral challenge (i.e. 90% effective, 50% effective, 10% effective) or duration of protection (two weeks, two months, two years, two decades). The Examiner has clearly stated the position of the Office by stating that this recitation is interpreted "to be inclusive of any expression level because the composition can comprise recombinant viral immunogen that has been purified and/or concentrated; therefore the amount of immunogen in the composition is not related to the level of expression in the plant.

(Ans. 12.) Therefore we give claim 1 its broadest reasonable interpretation,

consistent with that of the Examiner. Goodman suggests that antigens associated with viral pathogens could be expressed and that in some instances the recombinant protein can have a physiological effect on ingestion. (FF1 and 2.) This level of expression is sufficient to meet the expression level of claim 1.

Thus we conclude that the Examiner has set forth a prima facie case of obviousness on the evidence before us. The Appellants provide no reasonable alternative claim interpretation and provide no evidence of secondary considerations. The obviousness rejection is affirmed.

CONCLUSION OF LAW

The cited prior art teaches expressing an immunogen, in a plant at such a level that when a composition comprising the immunogen is consumed by an animal the composition elicits an immune response in the animal.

2. Claims 6 and 9 are rejected under 35 U.S.C. §103(a) for obviousness over Goodman in view of Kapikian, Kay and Gallie.

"Appellant[s] do not rely upon the features of claim 6 for separate patentability apart from the parent claim from which it depends" (App. Br. 10). For the reasons given in the Examiner's Answer and further discussed herein we have found that the cited references disclose the subject matter of claim 1.

CONCLUSION OF LAW

The cited references support the Examiner's obviousness rejection which has not been rebutted by Appellants with sufficient evidence.

TIME PERIOD

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

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